

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY


(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference R 43923 | | FOR FURTHER ACTION | | See Form PCT/IPEA/416 |
| International application No. PCT/EP2004/008580 | | International filing date (day/month/year) 30.07.2004 | Priority date (day/month/year) 11.08.2003 | |
| International Patent Classification (IPC) or national classification and IPC C12N15/82 | | | | |
| Applicant GREENOVATION BIOTECH GMBH et al. | | | | |
| <p>1. This report is the International preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (Indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> | | | | |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input checked="" type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p> | | | | |
| Date of submission of the demand 11.03.2005 | | Date of completion of this report 03.11.2005 | | |
| Name and mailing address of the International preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | | Authorized Officer Ury, A Telephone No. +49 89 2399-8411 | | |



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2004/008580

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-45 as originally filed

Sequence listings part of the description, Pages

1-31 as originally filed

Claims, Numbers

1-22 as originally filed

Drawings, Sheets

1/19-19/19 as originally filed

☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. II Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:
- ☐ copy of the earlier application whose priority has been claimed (Rule 66.7(a)).
 - ☐ translation of the earlier application whose priority has been claimed (Rule 66.7(b)).
2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1). Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:
- see separate sheet**

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|------|
| Novelty (N) | Yes: Claims | 3-22 |
| | No: Claims | 1-2 |
| Inventive step (IS) | Yes: Claims | 3-22 |
| | No: Claims | 1-2 |
| Industrial applicability (IA) | Yes: Claims | 1-22 |
| | No: Claims | |

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

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Supplemental Box relating to Sequence Listing

Continuation of Box I, item 2:

1. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this report has been established on the basis of:
 - a. type of material:
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☒ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing:
 - ☒ contained in the international application as filed
 - ☐ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purposes of search and/or examination
 - ☐ received by this Authority as an amendment on
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional observations, if necessary:

Reference is made to the following documents: D1-D5 as cited in the ISR.

The present application discloses moss derived expression regions or MEPR (promoters) allowing expression and production of peptides in genetically modified mosses host cells.

The prior art (see passages cited for D4 and D5) mentions the existence of moss promoters. 5' regions wherein sequences resembling to prokaryotic or eucaryotic promoter consensus sequences have been identified (see e.g. Fig.2 of D5). However, said 5' regions are merely putative promoters because no functional analysis has been performed on these regions and it remains unknown and questionable (in view of their short length) whether said 5' sequences identified in these prior art documents indeed function as promoters.

Additionally no cited document render obvious the specific MEPR sequences of the application.

Therefore, novelty, inventive step and unity of invention can be acknowledged for the SEQ ID of the application provided of course that said SEQ ID do indeed have the function of MEPR. In this respect the claims should be limited to the sequences for which a promoting activity has been demonstrated in the application. For instance all the SEQ ID corresponding to 3' regions do not have such an activity and should be deleted from the claims (e.g. SEQ ID NO:2, 4, 6, 8 etc...see page 44-45 of application). Please note that whether these 3' regions may or may not be regarded as expression regions is irrelevant since what is presently requested is a demonstration of an expression promoting activity.

Concerning the non-acceptable subject-matter (claims 1 and 2) the following objections are raised.

- Lack of technical feature (i.e. sequences). Claims 1-2 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result. It is clear from the description

that the features of the SEQ ID are essential to the definition of the invention. Since claim 1-2 do not contain these features they do not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any claim must contain all the technical features essential to the definition of the invention.

- Lack of novelty because said region are not defined by technical features and have no distinguishing technical feature over the putative promoter region identified in D5.

- Lack of inventive step: Due to the absence of technical features and considering the basic knowledge of the skilled person combined with for instance D1-D5 the subject-matter of these claims merely consists of a paraphrase of the technical problem (i.e. to provide suitable moss derived expression promoting means). There is no inventivity in formulating the problem to be solved as a solution. Indeed D1, D2 and D3, for instance, disclose the cDNA corresponding to moss genes. The mRNAs from which these cDNAs are derived were expressed via promoter sequences or promoting regions. It is a general rule for biological organisms that promoter regions are involved in the expression of mRNAs.

Of course all the other claims, except claim 3, are also not acceptable as long as they refer back to claims 1 and 2.